

ONETOUCH[®]

Vita[™]

Blood Glucose Monitoring System

USER GUIDE


















Replaces User's Handbook

Contents:

1	Setting up your system	1
2	Testing your blood glucose	5
3	Attaching meal flags and fasting flags to your test results	13
4	Reviewing past results and averages	15
5	Control solution testing	17
6	Care and maintenance	19
7	Troubleshooting and detailed information about your system	21

Symbols

	Caution: Refer to instructions for use
	Direct Current
	Low Battery
	Serial Number
	Lot Number
	Manufacturer
	Authorised Representative
	In Vitro Diagnostic Medical Device
	Expiry Date
	Sterilised by irradiation
	Storage temperature limits
	Consult instructions for use
	Contains sufficient for <n> tests
	Do not re-use
	Separate collection of batteries

The system described herein is covered by one or more of the following U.S. patents: 5,708,247, 5,951,836, 6,241,862, 6,284,125, and 7,112,265. Use of the monitoring device included herein is protected under one or more of the following U.S. patents: 6,413,410, 6,733,655, 7,250,105. Purchase of this device does not act to grant a use licence under these patents. Such a licence is granted only when the device is used with OneTouch® Vita™ Test Strips. No test strip supplier other than LifeScan is authorised to grant such a licence. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.

Call Customer Care on
0800 121 200 (UK)
or 1800 535 676 (Ireland)
Or visit us at www.LifeScan.co.uk



© 2009 LifeScan, Inc.



LifeScan self-test blood glucose monitoring devices conform to the following EU Directives:

IVDD (98/79/EC):



Blood Glucose Meter, Test Strips, and Control Solution.

MDD (93/42/EEC):



Lancets



Blood Sampler



LifeScan, Inc.
Milpitas, CA 95035 USA



LifeScan Regulatory Affairs Europe
Division of Ortho-Clinical Diagnostics France
1, rue Camille Desmoulins – TSA 40007
92787 Issy-les-Moulineaux, Cedex 09
France

Distributed by:
LifeScan UK/Ireland,
A div. of Ortho-Clinical Diagnostics,
Johnson & Johnson,
50 - 100 Holmers Farm Way,
High Wycombe, Bucks HP12 4DP
United Kingdom
www.LifeScan.co.uk

Made in China

Before you begin

Before using this product to test your blood glucose, carefully read this User Guide, and the inserts that come with the OneTouch® Vita™ Test Strips and OneTouch® Vita™ Control Solution.

Intended use

The OneTouch® Vita™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood. The OneTouch® Vita™ System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of diabetes or for testing newborns.

Test principle

Glucose in the blood sample mixes with special chemicals in the test strip and a small electric current is produced. The strength of this current changes with the amount of glucose in the blood sample. Your meter measures the current, calculates your blood glucose level, displays the result, and stores it in its memory.

The OneTouch® Vita™ Blood Glucose Monitoring System

INCLUDED WITH YOUR KIT:



OneTouch® Vita™ Meter
(battery included)

Carrying Case



OneTouch® Vita™ Test Strips



Sterile Lancet



Lancing Device

If the lancing device shown here is not included with your kit, see the user instructions for that lancing device.

AVAILABLE SEPARATELY:



Clear Cap



OneTouch® Vita™
Control Solution

Control solution is available free of charge from Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland)

⚠ WARNING: Keep the meter and testing supplies away from young children. Small items such as the battery door, battery, test strips, lancets, protective covers on the lancets, and control solution vial cap are choking hazards. Do not ingest or swallow any items.

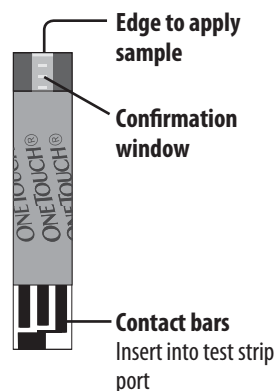
1 Setting up your system

The OneTouch® Vita™ Blood Glucose Meter and test strips

METER



TEST STRIP



Turning your meter on

Press and hold **OK** until the meter turns on. After the black start-up screen, the MAIN MENU appears.

MAIN MENU
LAST RESULT
ALL RESULTS
AVERAGES
SETTINGS
METER OFF

CAUTION: If you see any light areas within the black start-up screen, there may be a problem with the meter. Contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

Setting the meter language, date and time

Before using your meter for the first time, you should check these settings. When using the meter for the first time, you will automatically start at the LANGUAGE screen, then the SETTINGS screen.

1 Go to the SETTINGS screen

From the MAIN MENU, press  or  to highlight SETTINGS and press .

MAIN MENU
LAST RESULT
ALL RESULTS
AVERAGES
SETTINGS
METER OFF

Then, press  or  to select METER SETTINGS and press .

SETTINGS
METER SETTINGS
FLAGS
SERIAL NUMBER
MENU

If the pre-set language, date and time are correct, press  to return to the MAIN MENU.


If any setting is not correct, press  or  to select CHANGE and press  (go to step 2).

SETTINGS
ENGLISH
11/OCT/08
11:15
mmol/L
OK
CHANGE

2 Choose a language

Now press  or  to highlight the language you want and press .

Pressing  after making your selection confirms each setting and takes you to the next screen.

If at any point you make the wrong selection, simply press and hold  until the meter turns off. Then, turn the meter back on and re-start from step 1.

LANGUAGE
ENGLISH

3 Set the date

The date and time formats have been pre-set. You cannot change these settings.

In the DATE AND TIME screen, press  or  to change the year and press . Repeat these steps to set the month and day.

DATE AND TIME	
DATE:	11 / OCT / 2008
TIME:	11 : 15

4 Set the time of day


Press  or  to set the hour and press . Repeat this step to set the minutes.


DATE AND TIME	
DATE:	11 / OCT / 2008
TIME:	11 : 15

5 Confirm your settings

If your settings are correct, press  to save them and return to the MAIN MENU.

If not, press  or  to highlight CHANGE and press . You will return to the LANGUAGE screen.

SETTINGS	
ENGLISH	
11/OCT/08	
11:15	
mmol/L	
	
CHANGE	

 **WARNING:** The unit of measure mmol/L should be displayed here. If your display shows mg/dL rather than mmol/L, contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland). You cannot change the unit of measure. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

Checking the meter serial number

You can check your meter serial number at any time.

1 Go to the SERIAL NUMBER screen

From the MAIN MENU, press  or  to highlight SETTINGS and press .

Then press  or  to select SERIAL NUMBER and press .

SETTINGS
METER SETTINGS
FLAGS
SERIAL NUMBER
MENU

Your serial number is displayed. Press  to return to the MAIN MENU.

SERIAL NUMBER
LAXGL0Q6

Turning your meter off after setup

There are three ways to turn your meter off:

- Press and hold  for three seconds,

or,

- Your meter will turn off by itself if left alone for about two minutes,

or,

- From the MAIN MENU, press  or  to highlight METER OFF, then press .

2 Testing your blood glucose

Testing with a fingertip sample

Preparing for a test

Have these things ready when you test:

OneTouch® Vita™ Meter

OneTouch® Vita™ Test Strips

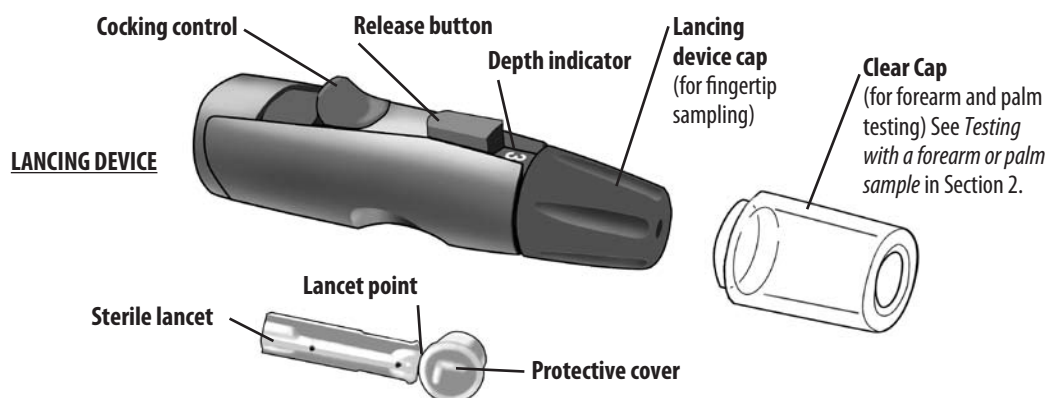
Lancing device

Sterile lancets

- Use only OneTouch® Vita™ Test Strips.
- Unlike some blood glucose meters, no separate step to code your OneTouch® Vita™ system is required.
- Make sure your meter and test strips are about the same temperature before you test.
- For the most accurate results, test as close to room temperature (20–25°C) as you can (see *Detailed information about your system* in Section 7).
- Tightly close the cap on the vial immediately after use to avoid contamination and damage.
- Store unused test strips only in their original vial.
- **Do not** open the test strip vial until you are ready to remove a test strip and perform a test. Use the test strip immediately after removing it from the vial.
- **Do not** return the used test strip to the vial after performing a test.
- **Do not** re-use a test strip that had blood or control solution applied to it. Test strips are for single use only.
- Write the discard date (6 months after first opening the vial) on the vial label when you first open it.

⚠ CAUTION:

- **Do not** use your test strips if your vial is damaged or left open to air. This could lead to error messages or inaccurate results. Contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland) immediately if the test strip vial is damaged.
- If you cannot test due to a problem with your testing supplies, contact your healthcare professional. Failure to test could delay treatment decisions and lead to a serious medical condition.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.
- **Do not** use test strips after the expiration date (printed on the vial) or the discard date, whichever comes first, or your results may be inaccurate.



If the lancing device shown here is not included with your kit, see the user instructions for that lancing device.

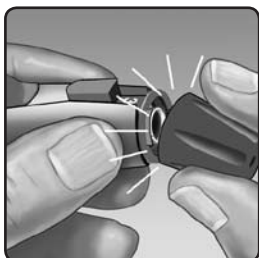
Always keep your meter and lancing device clean (see *Caring for your system* in Section 6.)

⚠ CAUTION: To reduce the chance of infection:

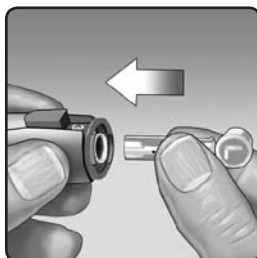
- Never share a lancet or a lancing device with anyone.
- Always use a new, sterile lancet each time you test.

Getting a blood sample from the fingertip

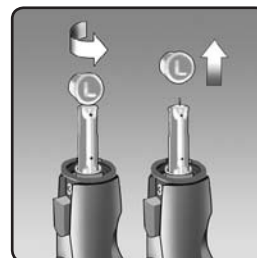
Before testing, wash your hands thoroughly with warm, soapy water. Rinse and dry.



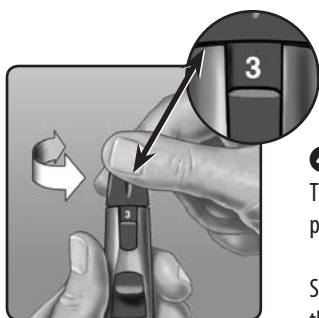
- 1 Snap off the lancing device cap**



- 2 Insert a sterile lancet**
Firmly push the lancet into the holder.



- 3 Twist off the protective cover and save it for later use.**
Replace the lancing device cap.



- 4 Adjust the depth setting**

Twist the lancing device cap until the desired setting appears. Smaller numbers are for shallower punctures, which may be less painful.

Shallower punctures work for children and most adults. Deeper punctures work well for people with thick or callused skin.



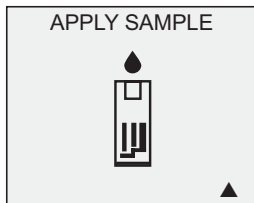
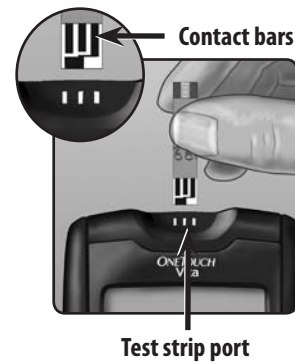
- 5 Cock the lancing device**

Slide the cocking control back until it clicks.

If it does not click, that's okay. It may have been cocked when you inserted the lancet.

6 Insert a test strip to turn the meter on

Insert a test strip into the test strip port as shown, with the contact bars facing you.



When the APPLY SAMPLE screen appears on the display, you can apply your blood sample.

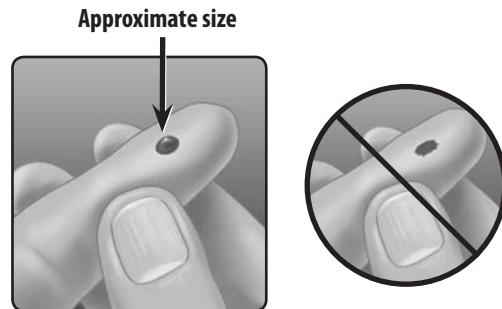


7 Lance your finger

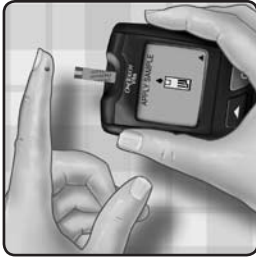
Hold the lancing device firmly against the side of your finger. Press the release button.

8 Get a round drop of blood

Gently squeeze your finger until you get a round drop of blood. If the blood smears or runs, **Do not** use that sample. Wipe the area and gently squeeze another drop of blood or puncture a new site.



Applying blood and reading results



Fingertip

1 Prepare to apply the sample

Keeping your finger extended and steady, move the meter and test strip toward the blood drop.



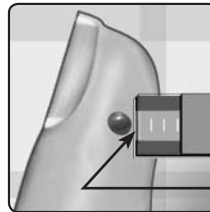
Do not apply blood on the top of the test strip.

Do not hold the meter and test strip underneath the blood drop. This may cause blood to run into the test strip port and damage the meter.

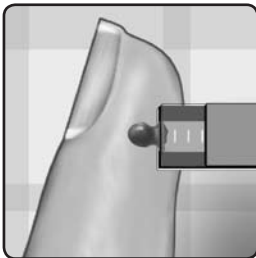
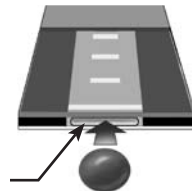


2 Apply the sample

Line up the test strip with the blood drop so that the narrow channel on the edge of the test strip is almost touching the edge of the blood drop.



Narrow channel



Gently touch the channel to the edge of the blood drop.

Be careful not to push the test strip against your fingertip or the test strip may not fill completely.



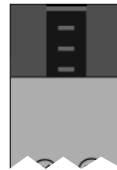
- **Do not** smear or scrape the drop of blood with the test strip.
- **Do not** apply more blood to the test strip after you have moved the drop of blood away.
- **Do not** move the test strip in the meter during a test.

⚠ CAUTION: You may get an ERROR 5 message or an inaccurate result if the blood sample does not fill the confirmation window completely. See *Troubleshooting* in Section 7. Discard the test strip and re-start the test process.

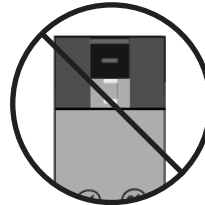
3 Wait for the confirmation window to fill completely

The blood drop will be drawn into the narrow channel and the confirmation window should fill completely.

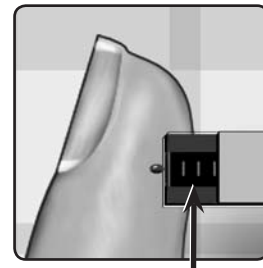
When the confirmation window is full, this means you have applied enough blood. Now you can move the test strip away from the blood drop and wait for the meter to count down from 5 to 1.



Full



Not full



Confirmation window full

4 Read your result on the meter

Your blood glucose level appears on the display, along with the unit of measure, and the date and time of the test.

If mmol/L does not appear with the test result, contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

After getting a result

Once you have your result, you may:

- Attach a meal flag or fasting flag to this result, see Section 3, Attaching meal flags and fasting flags to your test results
- or,
- Review your meter memory by pressing **OK**, see Section 4, Reviewing past results and averages
- or,
- Turn the meter off by removing the test strip.



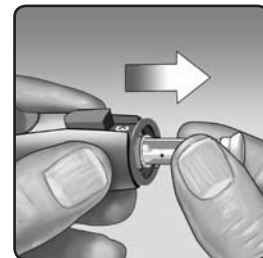
(Example)

Removing the used lancet

Remove the lancing device cap. Place the lancet protective cover on a hard surface and push the lancet tip into the cover. Remove the lancet and place it in a container for sharp objects. Replace the lancing device cap.

Disposing of the used lancet and test strip

It is important to discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your healthcare professional's recommendations or local regulations for proper disposal.



Interpreting unexpected test results

Refer to the following cautions whenever your test results are lower or higher than what you expect.

CAUTION:

Low glucose results

- If your test result is lower than 3.9 mmol/L or is shown as LOW GLUCOSE, it may mean hypoglycaemia (low blood glucose). Treat this condition immediately, according to your healthcare professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do another test.
- If you test at the low end of the operating range (10°C) and your blood glucose is high, you may get an inaccurate low result. Re-test in a warmer environment with a new test strip.

Dehydration and low glucose results

- You may get false low glucose results if you are severely dehydrated. If you think you are severely dehydrated, contact your healthcare professional immediately.

High glucose results

- If your test result is higher than 10.0 mmol/L, it may mean hyperglycaemia (high blood glucose) and you should consider re-testing. Talk to your healthcare professional if you are concerned about hyperglycaemia.
- HIGH GLUCOSE is displayed when your blood glucose level is higher than 33.3 mmol/L. You may have severe hyperglycaemia (very high blood glucose). Re-test your blood glucose. If the result is HIGH GLUCOSE again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional immediately.

Repeated unexpected glucose results


- If you continue to get unexpected results, check your system with control solution. See Section 5, Control solution testing.
- If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this User Guide, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes control programme without speaking to your healthcare professional.

Unusual red blood cell count

- A haematocrit (percentage of your blood that is red blood cells) that is either very high (above 55%) or very low (below 30%) can cause false results.

Testing with a forearm or palm sample

The OneTouch® Vita™ Meter lets you obtain a blood sample from your forearm or palm. Getting a drop of blood from these "alternate sites" may be less painful than a fingertip sample.

 **CAUTION:** Talk to your healthcare professional before using your forearm or palm for testing.

If you are testing:

Before or more than two hours after:

- a meal
- a rapid-acting insulin injection or insulin pump bolus
- exercise

Use blood sample from your:

Fingertip, forearm, or palm

⚠ CAUTION: Do not test on your forearm or palm when:

- You think your blood glucose is rapidly falling, such as within two hours of exercise or a rapid-acting insulin injection or insulin pump bolus. Testing with a fingertip sample may identify hypoglycaemia or an insulin reaction sooner than testing with a forearm or palm sample.
- It has been less than two hours after a meal, a rapid-acting insulin injection or insulin pump bolus, physical exercise, or you think your glucose level is changing rapidly.
- You are ill or during times of stress.
- You are concerned about the possibility of hypoglycaemia or an insulin reaction, such as when driving a car. This is especially important if you suffer from hypoglycaemia unawareness (lack of symptoms to indicate an insulin reaction).

Getting a blood sample

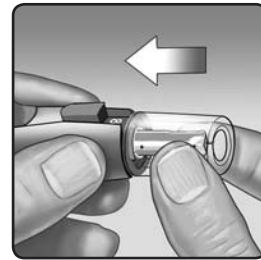
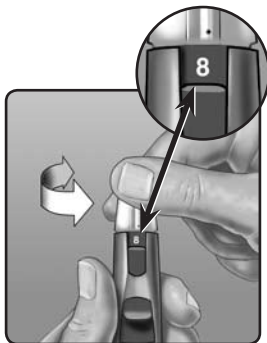
Getting a blood sample from your forearm or palm is different than getting a sample from your fingertips. Follow these instructions to get a sufficient blood drop for testing.

Before testing, make sure to wash the puncture site with soap and water. Rinse and dry thoroughly.

The clear cap is for forearm and palm sampling only. Replace the blue cap with the clear cap.

❶ Insert a lancet and snap on clear cap

Carefully insert a new, sterile lancet. Snap on the clear cap.



❷ Adjust the depth setting

You may need a deeper setting to get a sufficient sample for testing.

Twist the cap to increase the depth.

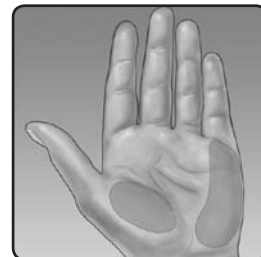
Be sure to cock the lancing device.

❸ Choose a sample site

- Choose a spot away from bone, veins, and hair. Massage the site to increase blood flow.
- Select a spot with no visible veins and avoid deep lines, which may cause your blood sample to smear.



Forearm



Palm

4 Lance your forearm or palm

- Firmly press and hold the lancing device against the sample site.
- Looking through the clear cap, you should see the sample site change colour as blood collects under the skin. This lets you know that there is adequate blood to obtain a sufficient sample for testing.



Forearm or Palm

- Press the release button while continuing to apply pressure.



Forearm or Palm



Forearm



Palm

- Keep holding the lancing device against your skin until a round drop of blood forms under the cap. **Do not** press on the site excessively.

5 Remove the lancing device

Carefully lift the lancing device away from your skin. **Do not** smear the blood sample.

If the drop of blood runs or spreads due to contact with hair or a line in your palm, **Do not** use the sample. Try lancing again in a smoother area.

If bruising occurs at an alternate site or you have difficulty getting a sample, consider sampling from a fingertip instead. You may want to review the choice of sites with your healthcare professional.

6 Apply the sample to the test strip

Keep your forearm or palm steady and use your other hand to bring the top edge of the test strip to the drop of blood.

- See *Testing with a fingertip sample* in Section 2 for more information on applying the blood sample to the test strip.
- See *Interpreting unexpected results* in Section 2 for more information on unexpected test results.
- See *Testing with a fingertip sample* in Section 2 for information on disposing the used lancet.



Forearm



Palm

3 Attaching meal flags and fasting flags to your test results

Turning the flags feature off

Your meter allows you to attach a before-meal, after-meal, or fasting flag to your blood glucose results.

A before-meal blood glucose test is taken just before the start of meal.

An after-meal blood glucose test is typically taken one to two hours after the start of your meal.

A fasting blood glucose test is taken after you have not eaten for at least 8 hours. Typically, this is the first test of the day.

You can also add or remove a meal flag when reviewing a past result in the meter memory.

Your meter comes pre-set with the flags feature turned on. If you do not want to use this feature, you can turn it off.

1 From the MAIN MENU, press  or  to select SETTINGS and press 

2 From the SETTINGS screen, select FLAGS and press 

SETTINGS
METER SETTINGS
FLAGS
SERIAL NUMBER
MENU

3 Press  to highlight YES, then press  to confirm the setting and return to the MAIN MENU

FLAGS
NOW SET TO:ON
CHANGE TO OFF?
NO
YES



We suggest you talk to your healthcare professional to see how meal flags and fasting flags may help you manage your diabetes.

Using the flags feature

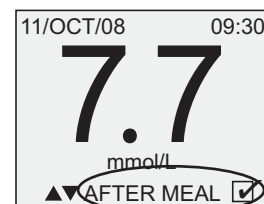
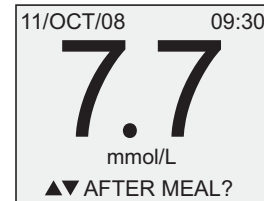
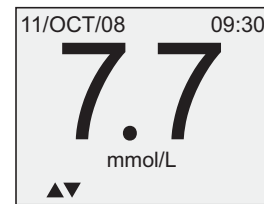
1 Adding a meal flag or fasting flag

To add any flag, the meal flag feature must be turned on.

When a glucose test result is displayed, the up/down arrows at the bottom left corner of the screen will flash.

Press  or  to select a flag and press .

Available flags are: [Blank] no flag
FASTING
BEFORE MEAL
AFTER MEAL






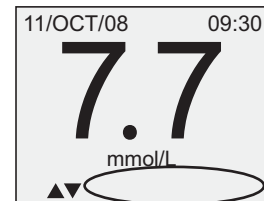
Indicates an after-meal flag is added

2 Choosing not to add a flag

If you do not want to add a flag, press  instead of  or . You will go to the MAIN MENU.

3 Removing a flag from a result

You can remove a flag from any test result. While your test result is displayed, press  or  until none of the flag options are displayed [Blank] and press . Your flag will be removed and you will go to the MAIN MENU.



Indicates no flag was added or flag is removed

4 Reviewing past results and averages

Reviewing past results and averages

If your meter is off, press and hold **OK** until the meter turns on. If you have just completed a test, press **OK** to get to the MAIN MENU.

From the MAIN MENU, choose:

- LAST RESULT to view your most recent result,
- ALL RESULTS to review up to 500 of your most recent results, or
- AVERAGES to select result averages.

Press **▲** or **▼** to highlight your selection and press **OK**.

MAIN MENU
LAST RESULT
ALL RESULTS
AVERAGES
SETTINGS
METER OFF

Last Result

The meter will display your most recent result.

Press **OK** to return to the MAIN MENU.

Date	Time
11/OCT/08	09:30
7.7	
mmol/L	
AFTER MEAL	
Unit of measure	Flag

All Results

The meter will display four results at a time, starting with the most recent.

The following symbols may also appear:

- HI** if the result was above 33.3 mmol/L
- LO** if the result was below 1.1 mmol/L
- C** if the result is from a control solution test
- if the result is flagged BEFORE MEAL
- +** if the result is flagged AFTER MEAL
- *** if the result is flagged FASTING

ALL RESULTS				
mmol/L				
11/OCT	10:01	C	6.8	
10/OCT	17:21		HI	
09/OCT	07:03	*	5.4	
08/OCT	08:33	+	7.7	
MENU				▲▼

When the meter memory is full, the oldest result is dropped as the newest is added

Press **▼** to move backward and **▲** to move forward through your results. Pressing and holding **▲** or **▼** allows you to move more quickly.

To view details of an individual result, press **▲** or **▼** to highlight the result, then press **OK**. If you wish to add or remove a meal flag for this result, see Section 3, Attaching meal flags and fasting flags to your test results.

To return to the previous screen, press **OK**.

To return to the MAIN MENU, highlight MENU, then press **OK**.

Averages

The meter will display three types of averages:

- ALL RESULTS AVG to view all test results
- MEAL AVGS to view before- and after-meal results
- FASTING AVG to view fasting results

AVERAGES
ALL RESULTS AVG
MEAL AVGS
FASTING AVG
MENU

All results average

If the meal flags feature is off, selecting AVERAGES from the MAIN MENU will lead directly to the ALL RESULTS AVG screen.

For each of the 7, 14 and 30 day periods leading up to the current date, the meter will display the number of results (NUM) and the average of these results (AVG).

Press **OK** to go back to the AVERAGES screen.

To return to the MAIN MENU, highlight MENU, then press **OK**.

ALL RESULTS AVG		
mmol/L		
LAST	NUM	AVG
7 DAYS	17	5.9
14 DAYS	30	6.3
30 DAYS	125	6.9
MENU		

Meal averages

The meter will display the averages of all before-meal (BFR) and after-meal (AFT) results for each of the 7, 14 and 30 day periods leading up to the current date. This screen is not available when the meal flags feature is off.

MEAL AVGS		
mmol/L		
LAST	BFR	AFT
7 DAYS	5.9	7.5
14 DAYS	6.4	7.8
30 DAYS	6.9	8.4
MENU		

Fasting average

For each of the 7, 14 and 30 day periods leading up to the current date, the meter will display the number of results (NUM) and the average of these results (AVG). This screen is not available when the flags feature is off.

- In result averages, a HI result is always counted as 33.3 mmol/L, and a LO result is always counted as 1.1 mmol/L. (See *Interpreting unexpected test results* in Section 2 for more information on high and low glucose results.)

FASTING AVG		
mmol/L		
LAST	NUM	AVG
7 DAYS	6	5.4
14 DAYS	21	5.5
30 DAYS	30	5.6
MENU		

- The meter calculates averages based on the 7, 14 and 30 day periods ending on the current date setting. If you change your date setting, your averages may change too.
- Result averages provide information from past results. **Do not** use result averages to make immediate treatment decisions.

Downloading results to a computer

You can store and analyse your test results by downloading them from the meter to a computer. For more information, or to obtain the required software and interface cable, visit www.LifeScan.co.uk or call Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland). Follow the installation instructions provided with the software, then connect the cable and transfer your data.

NOTE: Make sure the meter is turned off when you connect the cable to the meter data port. You will not be able to perform a test while the meter is downloading data.

⚠ WARNING: To avoid a possible shock, do not insert a test strip while the meter is connected to a computer.

5 Control solution testing

When to test with control solution

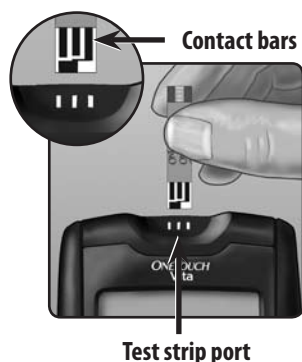
OneTouch® Vita™ Control Solution is used to practice the test and to check that the meter and test strips are working properly. (Control solution is available separately.)

⚠ CAUTION:

- **Do not** swallow control solution; it is not for human consumption.
- **Do not** apply control solution to the skin or eyes as it may cause irritation.

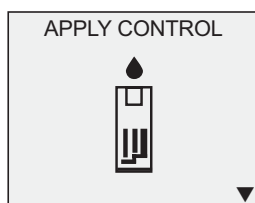
- Do a control test:
 - before performing your first blood glucose test.
 - whenever you open a new vial of test strips.
 - if you suspect that the meter and test strips are not working properly.
 - if you have repeated unexpected blood glucose results.
 - if you drop or damage the meter.
- Use only OneTouch® Vita™ Control Solution with your OneTouch® Vita™ Meter.
- Control solution tests must be done at room temperature (20–25°C). Make sure your meter, test strips, and control solution are at the same temperature before testing.
- When you open a new vial of control solution, record the discard date (date opened plus 3 months) on the vial label.
- Control solution is available free of charge from Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).
- Tightly close the cap on the control solution vial immediately after use to avoid contamination or damage.

How to test with control solution



1 Insert a test strip to turn the meter on

Wait for the APPLY SAMPLE screen to appear on the display.



2 Press to display the APPLY CONTROL screen

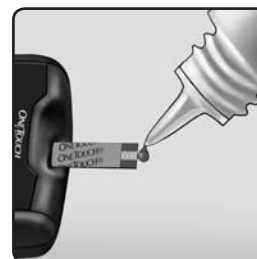
When the APPLY CONTROL screen is displayed, you can be sure that the test result will be correctly recorded in the meter memory as a control solution test.

3 Prepare and apply control solution

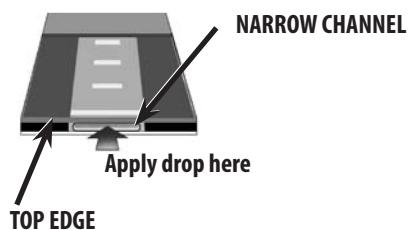
Shake the control solution vial and remove the cap.

Squeeze the vial to discard the first drop, then wipe the tip with a clean tissue or cloth.

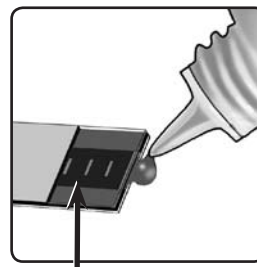
Touch and hold a hanging drop of control solution to the narrow channel in the **top edge** of the test strip.



Control solution should not be applied on top of the test strip.



When the confirmation window is full, the meter will count down from 5 to 1.



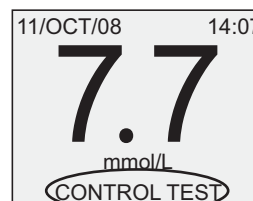
Confirmation window full

4 Read your result

Your control solution result will then appear on the display, along with the date, time, unit of measure, and the words CONTROL TEST.

Control solution results can be seen when reviewing past results, but are not included in result averages.

CAUTION: If the words **CONTROL TEST** do not appear on the screen, repeat the test with a new test strip. If the problem persists, contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).



(Example)

5 Check if the result is in range

Compare the result displayed on the meter to the OneTouch® Vita™ Control Solution range printed on the test strip vial.

If your control solution result falls outside the expected range, repeat the test with a new test strip.



OneTouch® Vita™
5.7–7.6 mmol/L

(Example range)

CAUTION:

- If you continue to get control solution test results that fall outside the range printed on the test strip vial, **Do not** use the meter, the test strips, or the control solution. Contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).
- The control solution range printed on the test strip vial is for OneTouch® Vita™ Control Solution only. It is not a recommended range for your blood glucose level.

Out-of-range results may be due to:

- not following the instructions detailed in steps 1–5,
- use of control solution that is contaminated, expired, or past its discard date,
- use of a test strip that is contaminated, damaged, expired, or past its discard date,
- a problem with the meter, or
- control solution test was performed outside the correct temperature range (20–25°C).

6 Care and maintenance

Changing the battery

Your OneTouch® Vita™ Meter uses one 3.0 Volt CR 2032 lithium battery (or equivalent).

See *Troubleshooting* in Section 7, for information on when to change the meter battery.

⚠ WARNING: To avoid a possible shock, Do not change the battery while the meter is connected to a computer.

1 Remove the old battery

Make sure the meter is turned off. Open the battery door and pull up on the battery ribbon.

Meter battery



Meter battery

2 Insert the new battery

With the "+" side facing up toward you, place the battery in the compartment within the fold of the ribbon.

Push the battery until it snaps into the battery clasp.

Replace the battery door.



If the meter does not power on after you have replaced the battery, check that the battery is correctly installed with the "+" side up. If the meter still does not power on, contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

3 Check your meter settings

Removing the meter battery will not affect your stored results, however, you may need to re-set your meter settings. (See *Setting the meter language, date and time* in Section 1.)

4 Dispose of battery

Dispose of batteries according to your local environmental regulations.



Please recycle or dispose of used batteries using your local battery collection systems and in compliance with your local environmental laws and regulations. Batteries contain chemicals that, if released, may affect the environment and human health. The crossed-out wheelie-bin symbol indicates the need for the separate collection for batteries.

Caring for your system

Storing your system


Store your meter, test strips, control solution, and other items in your carrying case. Keep in a cool, dry place between 4°C and 30°C, but **Do not** refrigerate. Keep all items away from direct sunlight and heat.

OneTouch® Vita™ Test Strips

With clean, dry hands, you may touch the test strip anywhere on its surface. **Do not** bend, cut, or modify the test strips in any way.

Checking for expiration or damage to test strips and control solution

Expiration dates for test strips and control solutions are printed on their vial labels. When you first open a new vial of test strips or control solution, record the discard date on the label. Refer to the test strip insert or control solution insert for instructions on determining the discard date.

 **CAUTION:** Do not use the test strips or control solution after the expiration date or the discard date, whichever comes first, or your results may be inaccurate.

Cleaning and caring for your meter

Wipe the outside with a soft cloth dampened with water and mild detergent to remove dirt or other contaminants.

To avoid damaging your meter:

- **Do not** use alcohol or another solvent.
- **Do not** allow liquids, dirt, dust, blood, or control solution to enter the test strip port or the data port. (Refer to meter illustration in Section 1, Setting up your system.)
- **Do not** spray cleaning solution on the meter or immerse it in any liquid.

Cleaning your lancing device and clear cap

To clean these items, wipe them with a soft cloth dampened with water and mild detergent to remove dirt or other contaminants.

Do not immerse the lancing device in any liquid, as it may damage your lancing device.

To disinfect these items, prepare a solution of one part household bleach to ten parts water. Wipe the lancing device with a soft cloth dampened with this solution. Immerse the **caps only** in this solution for 30 minutes. Rinse briefly with water and allow both to air dry.

7 Troubleshooting and detailed information about your system

Troubleshooting







The OneTouch® Vita™ Meter displays messages when there are problems with the test strip, with the meter, or when your blood glucose levels are higher than 33.3 mmol/L or lower than 1.1 mmol/L. Improper use may cause an inaccurate result without producing an error message.




In this section, screens that display "SEE USER'S HANDBOOK" means you should refer to this User Guide.

Message	What it means	What to do
<div> <div>WARNING</div> <div> LOW GLUCOSE BELOW 1.1 mmol/L </div> <div>▲▼</div> </div>	You may have a very low blood glucose level (severe hypoglycaemia), lower than 1.1 mmol/L.	This may require immediate treatment according to your healthcare professional's recommendations. Although this message could be due to a test error, it is safer to treat first and then do another test.
<div> <div>WARNING</div> <div> HIGH GLUCOSE ABOVE 33.3 mmol/L </div> <div>▲▼</div> </div>	You may have a very high blood glucose level (severe hyperglycaemia), above 33.3 mmol/L.	Re-test your blood glucose. If the result is HIGH GLUCOSE again, obtain and follow instructions from your healthcare professional without delay.
<div> <div>WARNING</div> <div> LOW GLUCOSE BELOW 1.1 mmol/L CONTROL TEST </div> </div>	Your control solution test result is below 1.1 mmol/L.	Test again with control solution and a new test strip. If the result is LOW GLUCOSE again, do not use the meter. Contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

Message	What it means	What to do
<div> <div>WARNING</div> <div> HIGH GLUCOSE ABOVE 33.3 mmol/L CONTROL TEST </div> </div>	Your control solution test result is above 33.3 mmol/L.	Test again with control solution and a new test strip. If the result is HIGH GLUCOSE again, do not use the meter. Contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).
<div> <div>WARNING</div> <div> TEMPERATURE ERROR TEMPERATURE TOO HIGH SEE USER'S HANDBOOK </div> </div>	Meter is too hot (above 44°C) to work correctly.	Move the meter and test strips to a cooler area. Insert a new test strip when the meter and test strips are within the operating range (10–44°C). If you do not get another TEMPERATURE ERROR message, you can proceed with testing.
<div> <div>WARNING</div> <div> TEMPERATURE ERROR TEMPERATURE TOO LOW SEE USER'S HANDBOOK </div> </div>	Meter is too cold (below 10°C) to work correctly.	Move the meter and test strips to a warmer area. Insert a new test strip when the meter and test strips are within the operating range (10–44°C). If you do not get another TEMPERATURE ERROR message, you can proceed with testing.
<div> <div>WARNING</div> <div> ERROR 1 METER PROBLEM CONTACT CUSTOMER SERVICE </div> </div>	There is a problem with the meter.	Do not use the meter. Contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).

Message	What it means	What to do
<div>WARNING</div> <div>ERROR 2</div> <div>METER OR STRIP PROBLEM</div> <div>RETEST WITH A NEW STRIP</div>	Error message could be caused either by a used/damaged test strip or a problem with the meter.	Repeat the test with a new test strip; see <i>Applying blood and reading results</i> in Section 2 or Section 5, Control solution testing. Contact Customer Care on 0800 121 (UK) or 1800 355 676 (ireland).
<div>WARNING</div> <div>ERROR 3</div> <div>METER WAS NOT READY</div> <div>RETEST WITH A NEW STRIP</div>	The sample was applied before the meter was ready. If this message continues to appear contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland)	Repeat the test with a new test strip. Apply a blood or control solution sample only after APPLY SAMPLE or APPLY CONTROL appears on the display. If this message continues to appear, contact Customer Care on 0800 121 (UK) or 1800 355 676 (ireland).
<div>WARNING</div> <div>ERROR 4</div> <div>STRIP PROBLEM</div> <div>SEE USER'S HANDBOOK</div>	<p>One of the following may apply:</p> <p>You may have tested in an environment near the low end of the system's operating range.</p> <p>or,</p> <p>The test strip may have been damaged or moved during testing.</p> <p>or,</p> <p>The sample was improperly applied.</p> <p>or,</p> <p>There may be a problem with the meter.</p>	Make sure you are testing within the operating range (10–44°C) and repeat the test with a new test strip; see <i>Applying blood and reading results</i> in Section 2 or Section 5, Control solution testing. If this message continues to appear contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).
<div>WARNING</div> <div>ERROR 5</div> <div>STRIP PROBLEM OR SAMPLE TOO SMALL</div> <div>RETEST WITH A NEW STRIP</div>	The meter has detected a problem with the test strip. Possible causes are test strip damage or an incompletely filled confirmation window.	Repeat the test with a new test strip. See <i>Applying blood and reading results</i> in Section 2 or Section 5, Control solution testing for instructions on properly filling the confirmation window. Contact Customer Care on 0800 121 200 (UK) or 1800 535 676 (Ireland).
<div>WARNING</div> <div></div> <div>LOW BATTERY</div> <div>REPLACE BATTERY SOON</div> <div>SEE USER'S HANDBOOK</div>	Meter battery is low but still has enough power to perform a test.	This message will appear when you turn the meter on and there is enough power for a minimum of 100 more tests. Press  to continue, but replace the battery as soon as possible; see <i>Changing the battery</i> in Section 6.
<div>11/OCT/08 09:30</div> <div>7.7</div> <div>mmol/L</div> <div>   AFTER MEAL </div>	Meter battery is low but still has enough power to perform a test.	Once the LOW BATTERY/REPLACE BATTERY SOON message is displayed, this symbol will continue to appear until you replace the battery. Test results will still be accurate, but replace the battery as soon as possible; see <i>Changing the battery</i> in Section 6.

Message	What it means	What to do															
<div> <div>WARNING</div> <div>  </div> <div>LOW BATTERY</div> <div>REPLACE BATTERY NOW!</div> <div>SEE USER'S HANDBOOK</div> </div>	Meter battery does not have enough power to perform a test.	Replace meter battery; see <i>Changing the battery</i> in Section 6.															
<div>NO DATA</div>	No result in memory, such as the first time use of the meter, or your meter was unable to recall this result. This result will not be included in result averages.	You can still perform a blood glucose test and get an accurate result.															
<div> <div>ALL RESULTS</div> <div>mmol/L</div> <table> <tr> <td>04/OCT</td> <td>09:44</td> <td>LO</td> </tr> <tr> <td>03/OCT</td> <td>13:23</td> <td>5.0</td> </tr> <tr> <td colspan="3">NO DATA</td></tr> <tr> <td>01/OCT</td> <td>10:12</td> <td>HI</td> </tr> <tr> <td colspan="3">MENU</td></tr> </table> </div>	04/OCT	09:44	LO	03/OCT	13:23	5.0	NO DATA			01/OCT	10:12	HI	MENU			Your meter was unable to recall this result. This result will not be included in result averages since there are no results in memory to display.	You can still perform a blood glucose test and get an accurate result.
04/OCT	09:44	LO															
03/OCT	13:23	5.0															
NO DATA																	
01/OCT	10:12	HI															
MENU																	
<div> <div>MEAL AVGS</div> <div>mmol/L</div> <table> <tr> <td>LAST</td> <td>BFR</td> <td>AFT</td> </tr> <tr> <td>7 DAYS</td> <td>---</td> <td>---</td> </tr> <tr> <td>14 DAYS</td> <td>6.4</td> <td>7.8</td> </tr> <tr> <td>30 DAYS</td> <td>6.9</td> <td>8.4</td> </tr> <tr> <td colspan="3">MENU</td></tr> </table> </div>	LAST	BFR	AFT	7 DAYS	---	---	14 DAYS	6.4	7.8	30 DAYS	6.9	8.4	MENU				
LAST	BFR	AFT															
7 DAYS	---	---															
14 DAYS	6.4	7.8															
30 DAYS	6.9	8.4															
MENU																	
<div> <div>FASTING AVG</div> <div>mmol/L</div> <table> <tr> <td>LAST</td> <td>NUM</td> <td>AVG</td> </tr> <tr> <td>7 DAYS</td> <td>0</td> <td>---</td> </tr> <tr> <td>14 DAYS</td> <td>21</td> <td>5.5</td> </tr> <tr> <td>30 DAYS</td> <td>30</td> <td>5.6</td> </tr> <tr> <td colspan="3">MENU</td></tr> </table> </div>	LAST	NUM	AVG	7 DAYS	0	---	14 DAYS	21	5.5	30 DAYS	30	5.6	MENU				
LAST	NUM	AVG															
7 DAYS	0	---															
14 DAYS	21	5.5															
30 DAYS	30	5.6															
MENU																	

Detailed information about your system

Technical specifications

Reported result range	1.1–33.3 mmol/L
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Test time	5 seconds
Assay method	Glucose oxidase biosensor
Meter power source	One 3.0 Volt CR 2032 lithium battery or equivalent
Unit of measure	mmol/L
Memory	500 test results

Automatic shutoff

About 2 minutes after last action

Size

95 x 65 x 25 mm

Weight

Approximately 58 grams, with battery

Operating ranges

Temperature: 10–44°C

Relative humidity: 10–90%

Altitude: up to 3048 metres

Haematocrit: 30–55%

Battery ratings

1 x 3.0 V d.c., 60 mA

(1 x CR 2032 battery or equivalent)

== direct current

System Accuracy

Diabetes experts have suggested that glucose meters should agree within 0.83 mmol/L of a laboratory method when the glucose concentration is lower than 4.2 mmol/L, and within 20% of a laboratory method when the glucose concentration is 4.2 mmol/L or higher. Samples from 100 diabetic patients at 1 clinical center were tested using both the OneTouch® Vita™ System and the YSI Model 2300 Glucose Analyser (laboratory test).

System Accuracy Results for Glucose Concentrations <4.2 mmol/L

Percent (and number) of meter results that match the laboratory test

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
56.1% (37/66)	89.4% (59/66)	98.5% (65/66)

System Accuracy Results for Glucose Concentrations ≥ 4.2 mmol/L

Percent (and number) of meter results that match the laboratory test

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
38.2% (204/534)	71.7% (383/534)	89.5% (478/534)	97.9% (523/534)

System Accuracy Results across the entire Glucose Range

Percent (and number) of meter results that match the laboratory test

Within ± 0.83 mmol/L or $\pm 20\%$
98.0% (588/600)

Therefore, 98% of the total results obtained with the OneTouch® Vita™ System achieved the goal suggested by the diabetes experts.

Regression Statistics

Samples were tested in duplicate on each of three test strip lots. Results indicate that the OneTouch® Vita™ System compares well with a laboratory method.

Number of Subjects	Number of Tests	Slope	Intercept (mmol/L)
100	600	1.033	- 0.596
95% CI Slope	95% CI Intercept (mmol/L)	Std. Error ($S_{y,x}$) (mmol/L)	R ²
(1.020, 1.046)	(-0.742, -0.449)	0.90449	0.977

Precision

Within Run Precision (100 venous blood tests per glucose level)

Target Glucose (mmol/L)	Mean Glucose (mmol/L)	Standard deviation (mmol/L)	Coefficient of variation (%)
2.2	2.2	0.1	3.5
5.6	5.7	0.1	1.7
7.2	7.7	0.1	1.9
11.1	12.7	0.2	1.3
16.7	19.6	0.3	1.5

Total Precision (200 control solution tests per glucose level)

Glucose Levels (mmol/L)	Mean Glucose (mmol/L)	Standard deviation (mmol/L)	Coefficient of variation (%)
LOW	2.2	0.1	3.3
MID	6.1	0.1	1.8
HIGH	19.6	0.3	1.5

Results show that the greatest variability observed between test strips when tested with blood is 3.5% or less.

Electrical and safety standards

This meter complies with CISPR 11: 2003, Class B (Radiated Only). Emissions of the energy used are low and not likely to cause interference in nearby electronic equipment. The meter has been tested for immunity to Level 3 electrostatic discharge as specified in IEC 61000-4-2. This meter has been tested for immunity to radio frequency interference over the frequency range 80 MHz to 2.5 GHz at 3 V/m as specified in IEC 61000-4-3. Degree of protection rating: IP31

Guarantee

LifeScan guarantees that the OneTouch® Vita™ Meter will be free of defects in material and workmanship for three years, valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable.